have actual knowledge that the information could be used, alone or in combination with other information that is reasonably available to the intended recipient, to identify the particular provider or reporter.

(3) *Re-identification*. A provider, PSO, or responsible person may assign a code or other means of record identification to allow information made nonidentifiable under this section to be re-identified by such provider, PSO, or responsible person, provided that:

(i) The code or other means of record identification is not derived from or related to information about the provider or reporter and is not otherwise capable of being translated so as to identify the provider or reporter; and

(ii) The provider, PSO, or responsible person does not use or disclose the code or other means of record identification for any other purpose, and does not disclose the mechanism for re-identification.

(b) Patient safety work product is non-identifiable with respect to a particular patient only if the individually identifiable health information regarding that patient is de-identified in accordance with the HIPAA Privacy Rule standard and implementation specifications for the de-identification at 45 CFR 164.514(a) through (c).

Subpart D—Enforcement Program

§ 3.304 Principles for achieving compliance.

(a) *Cooperation*. The Secretary will, to the extent practicable, seek the cooperation of providers, PSOs, and responsible persons in obtaining compliance with the applicable confidentiality provisions.

(b) *Assistance*. The Secretary may provide technical assistance to providers, PSOs, and responsible persons to help them comply voluntarily with the applicable confidentiality provisions.

§ 3.306 Complaints to the Secretary.

(a) *Right to file a complaint*. A person who believes that patient safety work product has been disclosed in violation of the confidentiality provisions may file a complaint with the Secretary.

(b) *Requirements for filing complaints*. Complaints under this section must meet the following requirements:

(1) A complaint must be filed in writing, either on paper or electronically.

(2) A complaint must name the person that is the subject of the complaint and describe the act(s) believed to be in violation of the applicable confidentiality provision(s).

(3) A complaint must be filed within 180 days of when the complainant knew or should have known that the act complained of occurred, unless this time limit is waived by the Secretary for good cause shown.

(4) The Secretary may prescribe additional procedures for the filing of complaints, as well as the place and manner of filing, by notice in the FEDERAL REGISTER.

(c) *Investigation*. The Secretary may investigate complaints filed under this section. Such investigation may include a review of the pertinent policies, procedures, or practices of the respondent and of the circumstances regarding any alleged violation. At the time of initial written communication with the respondent about the complaint, the Secretary will describe the act(s) that are the basis of the complaint.

§ 3.308 Compliance reviews.

The Secretary may conduct compliance reviews to determine whether a respondent is complying with the applicable confidentiality provisions.

§ 3.310 Responsibilities of respondents.

(a) *Provide records and compliance reports*. A respondent must keep such records and submit such compliance reports, in such time and manner and containing such information, as the Secretary may determine to be necessary to enable the Secretary to ascertain whether the respondent has complied or is complying with the applicable confidentiality provisions.

(b) *Cooperate with complaint investigations and compliance reviews*. A respondent must cooperate with the Secretary, if the Secretary undertakes an investigation or compliance review of the policies, procedures, or practices of the respondent to determine whether it is complying with the applicable confidentiality provisions.

(c) *Permit access to information.* (1) A respondent must permit access by the Secretary during normal business hours to its facilities, books, records, accounts, and other sources of information, including patient safety work product, that are pertinent to ascertaining compliance with the applicable confidentiality provisions. If the Secretary determines that exigent circumstances exist, such as when documents may be hidden or destroyed, a respondent must permit access by the Secretary at any time and without notice.

(2) If any information required of a respondent under this section is in the exclusive possession of any other agency, institution, or person, and the other agency, institution, or person fails or refuses to furnish the information, the respondent must so certify and set forth what efforts it has made to obtain the information.

§ 3.312 Secretarial action regarding complaints and compliance reviews.

(a) *Resolution when noncompliance is indicated.* (1) If an investigation of a complaint pursuant to § 3.306 of this subpart or a compliance review pursuant to § 3.308 of this subpart indicates noncompliance, the Secretary may attempt to reach a resolution of the matter satisfactory to the Secretary by informal means. Informal means may include demonstrated compliance or a completed corrective action plan or other agreement.

(2) If the matter is resolved by informal means, the Secretary will so inform the respondent and, if the matter arose from a complaint, the complainant, in writing.

(3) If the matter is not resolved by informal means, the Secretary will—

(i) So inform the respondent and provide the respondent an opportunity to submit written evidence of any mitigating factors. The respondent must submit any evidence to the Secretary within 30 days (computed in the same manner as prescribed under § 3.526 of this subpart) of receipt of such notification; and

(ii) If, following action pursuant to paragraph (a)(3)(i) of this section, the Secretary decides that a civil money penalty should be imposed, inform the respondent of such finding in a notice of proposed determination in accordance with § 3.420 of this subpart.

(b) *Resolution when no violation is found.* If, after an investigation pursuant to § 3.306 of this subpart or a compliance review pursuant to § 3.308 of this subpart, the Secretary determines that further action is not warranted, the Secretary will so inform the respondent and, if the matter arose from a complaint, the complainant, in writing.

(c) *Uses and disclosures of information obtained.* (1) Identifiable patient safety work product obtained by the Secretary in connection with an investigation or compliance review under this subpart will not be disclosed by the Secretary, except in accordance with § 3.206(d) of this subpart, or if otherwise permitted by this part or the Patient Safety Act.

(2) Except as provided for in paragraph (c)(1) of this section, information, including testimony and other evidence, obtained by the Secretary in connection with an investigation or compliance review under this subpart may be used by HHS in any of its activities and may be used or offered into evidence in any administrative or judicial proceeding.

§ 3.314 Investigational subpoenas and inquiries.

(a) The Secretary may issue subpoenas in accordance with 42 U.S.C. 405(d) and (e), and 1320a–7a(j), to require the attendance and testimony of witnesses and the production of any other evidence including patient safety work product during an investigation or compliance review pursuant to this part.

(1) A subpoena issued under this paragraph must—

(i) State the name of the person (including the entity, if applicable) to whom the subpoena is addressed;

(ii) State the statutory authority for the subpoena;

(iii) Indicate the date, time, and place that the testimony will take place;

(iv) Include a reasonably specific description of any documents or items required to be produced; and